

AMENDMENTS TO THE CLAIMS:

Claim 1. (Currently Amended) An antibiotic composition comprising coated micropellets and optionally one or more excipients, wherein said coated micropellets comprise

(i) a core comprising at least one antibiotic including clarithromycin;

(ii) an inner coating comprising at least one cellulose polymer which is not an enteric coating polymer; and

(iii) an outer coating comprising at least one enteric coating polymer, wherein said coated micropellets have a mean particle size of about 100 μm to about 650 μm .

Claim 2. (Original) The composition according to Claim 1, wherein the coated micropellets have a mean particle size of about 200 μm to about 500 μm .

Claim 3. (Original) The composition according to Claim 1, wherein at least about 90% of the coated micropellets have a particle size of about 100 μm to about 650 μm .

Claim 4. (Original) The composition according to Claim 1, wherein the cellulose polymer is selected from the group consisting of hydroxypropylmethyl cellulose, hydroxypropyl cellulose, methyl cellulose, ethyl cellulose, carboxymethylcellulose, sodium carboxymethyl cellulose, ethylcarboxyethyl cellulose, and combinations thereof.

Claim 5. (Original) The composition according to Claim 1, wherein the inner coating additionally comprises at least one plasticizer.

Claim 6. (Original) The composition according to Claim 5, wherein the plasticizer is selected from the group consisting of acetyl-triethyl citrate, acetyl tributyl-, tributyl-, triethylcitrate, glycerol diacetate, glycerol triacetate, acetylated monoglycerides, castor oil, dibutyl-phthalate, diethyl-phthalate, diethyl-phthalate, dimethyl-phthalate, dipropyl-phthalate, di-(2-methoxy- or 2- ethoxyethyl)-phthalate, ethylphthalyl glycolate, butylphthalylethyl glycolate, butylglycolate, propylene glycol, polyethylene glycol, diethyladipate, di- (2-methoxy- or 2-ethoxyethyl)- adipate, benzophenone, diethyl-and diburylsebacate, dibutylsuccinate, dibutyltartrate, diethylene glycol dipropionate, ethyleneglycol diacetate, ethyleneglycol dibutyrate, ethyleneglycol dipropionate, tributyl phosphate, tributyrin, polyethylene glycol sorbitan monooleate, sorbitan monooleate, and combinations thereof.

Claim 7. (Original) The composition according to Claim 6, wherein the plasticizer is polyethylene glycol.

Claim 8. (Original) The composition according to Claim 1, wherein the enteric coating polymer is selected from the group consisting of cross-linked polyvinyl pyrrolidone; non-cross linked polyvinylpyrrolidone; hydroxypropylmethyl cellulose phthalate; hydroxypropylmethyl cellulose acetate succinate, cellulose acetate succinate; cellulose acetate phthalate, hydroxypropylmethyl cellulose acetate succinate, cellulose acetate trimellitate, hydroxypropyl methyl cellulose phthalate; hydroxypropyl methyl cellulose acetate succinate; starch acetate phthalate; polyvinyl acetate phthalate; carboxymethyl cellulose; methyl cellulose phthalate; methyl cellulose succinate; methyl cellulose phthalate succinate; methyl cellulose phthalic acid half ester; ethyl cellulose succinate; carboxymethylamide; potassium methacrylatedivinylbenzene copolymer; polyvinylalcohols; polyoxymethyleneglycols; polyethylene glycol; sodium alginate; galactomannone; carboxypolymethylene; sodium carboxymethyl starch; copolymers of acrylic acid and/or methacrylic acid with at least one monomer selected from the group consisting of methyl methacrylate, ethyl methacrylate, ethyl acrylate, butyl methacrylate, hexyl methacrylate, decyl methacrylate, lauryl methacrylate, phenyl methacrylate, methyl acrylate, isopropyl acrylate, isobutyl acrylate, and octadecyl acrylate; polyvinyl acetate; fats; oils; waxes; fatty alcohols; shellac; gluten; ethylacrylate-maleic acid anhydride copolymer; maleic acid anhydride-vinyl methyl ether copolymer; styrol-maleic acid copolymer; 2-ethyl-hexyl-acrylate maleic acid anhydride; crotonic acid-vinyl acetate copolymer; glutaminic acid/glutamic acid ester copolymer; carboxymethylcellulose glycerol monoctanoate; polyarginine; poly(ethylene); poly(propylene); poly(ethylene oxide); poly(ethylene terephthalate); poly(vinyl isobutyl ether); poly(vinyl chloride); polyurethane, and combinations thereof.

Claim 9. (Original) The composition according to Claim 8, wherein the enteric coating polymer is selected from the group consisting of a copolymer of methacrylic acid and methyl methacrylate, and a copolymer of methacrylic acid and ethyl acrylate.

Claim 10. (Original) The composition according to Claim 1, wherein the outer coating additionally comprises at least one plasticizer.

Claim 11. (Original) The composition according to Claim 10, wherein the plasticizer is triethyl citrate and glycerol monostearate.

Claim 12. (Cancelled).

Claim 13. (Currently Amended) An oral suspension comprising (a) an antibiotic composition which comprises coated micropellets and optionally one or more excipients, (b) additional excipients, and (c) a liquid medium, wherein said coated micropellets comprise

(i) a core comprising at least one antibiotic including clarithromycin;

(ii) an inner coating comprising at least one cellulose polymer which is not an enteric coating polymer; and

(iii) an outer coating comprising at least one enteric coating polymer, wherein said coated micropellets have a mean particle size of about 100 μm to about 650 μm .

Claim 14. (Previously Presented) The oral suspension according to Claim 13, wherein the liquid medium is an aqueous medium.

Claim 15. (Currently Amended) A method for preparing an antibiotic composition comprising coated micropellets and optionally one or more excipients, said method comprising

(A) providing a core material containing comprising at least one antibiotic including clarithromycin[[.]] and, optionally, one or more excipients;

(B) adding mixing a solvent, and optionally one or more excipients, to with the core material of Step (A) to provide a mixture and granulating the mixture in the presence of an impeller set operating at a speed of at least at 50 rpm[[.]] to intimately mix the materials to form a wet granulation;

(C) drying the wet granulation to provide dried granules[[.]] and, optionally, milling and screening the dried granules to form micropellets; and

(D) coating the micropellets with an inner coating comprising at least one cellulose polymer which is not an enteric coating polymer to provide inner-coated micropellets wherein the inner coating thereof comprises at least a cellulose polymer; and

(E) coating the inner-coated micropellets from Step (D) with an outer coating comprising at least one enteric coating polymer to form coated micropellets; provide outer-coated micropellets wherein the outer coating comprises at least an enteric coating and wherein said outer coated micropellets have a mean particle size of about 100 μm to about 650 μm .

Claim 16. (Currently Amended) The method according to Claim 15, wherein the granulation Step (B) including mixing and granulating the material is additionally conducted in the presence of a chopper wherein the chopper is operated to chop and, hence, reduce the

size of particles in the granulation and wherein the combined action of the impeller and the chopper is carried out so as to both mix the granulation materials, at least in part, by the action of the impeller and to reduce the particle size of the granulation by the action of the chopper.

Claim 17. (Currently Amended) The method according to Claim 16, wherein the chopper is set at operates at a speed of at least 1000 rpm.

Claim 18. (Previously Presented) The method according to Claim 15, wherein the core material of Step (A) is provided by mixing the at least one antibiotic with at least one or more excipients to form the core material as a premix, and wherein the solvent added in Step (B) is added, optionally with one or more excipients, to the premix to provide the mixture for granulation.

Claim 19. (Previously Presented) The method of Claim 15, further comprising mixing the coated micropellets with an aqueous medium to form a suspension including at least the coated microspheres, wherein the suspension may be taken orally by a subject in need thereof.